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Ambient Water Quality Criteria Document Addendum for Acenaphthene

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ADDENDUM FOR ACENAPHTHENE

Prepared for

OFFICE OF WATER REGULATIONS
AND STANDARDS

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
CRAVE	Carcinogen risk assessment verification endeavor
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
ppm	Parts per million
RfD	Reference dose
RQ	Reportable quantity

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multi-stage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on acenaphthene, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1987 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

No teratogenicity studies have been reported, and the carcinogenic properties of acenaphthene remain undefined, with the chemical categorized in EPA Group D and IARC Group 3 (U.S. EPA, 1987). However, recent toxicity data are available for the derivation of ambient water quality criteria for acenaphthene (U.S. EPA, 1989). In an oral subchronic toxicity study (U.S. EPA, 1989), groups of CDI (ICR) BR mice (20/sex/group) were gavaged daily with 0, 175, 350 or 700 mg/kg/day acenaphthene for 90 days. Toxicological parameters evaluated included body weight, food consumption, mortality clinical chemistry and toxicity, hematology, ophthalmology, organ weights, and gross and histopathology. No treatment-related effects in survival, clinical toxicity, mean body weights, food consumption or ophthalmology were observed.

Significant dose-related organ weight changes were seen in both male and female mice at the mid- and high-dose levels (350 or 700 mg/kg/day). In males, significant decreases in absolute spleen weights were found. Significant decreases in relative ovary and adrenal weights were observed in females exposed at the two highest doses. In both males and females there was a significant increase in absolute and relative liver weight. This increase was associated with significant increases in cholesterol levels and centrilobular hepatocellular hypertrophy.

A significant increase in absolute liver weight was also reported in the low-dose female mice only; however, this increase was not associated with increased levels of cholesterol or hepatotoxicity.

Based on the results of this study, 175 mg/kg/day is considered a NOAEL and the 350 mg/kg/day dose a LOAEL for hepatotoxicity.

Bioconcentration Factor (BCF)

U.S. EPA (1980) estimated a BCF value of 242 for acenaphthene. Revisions for the estimation of a bioconcentration factor for acenaphthene are under review at this time. When these revisions are final the new BCF value will be incorporated into this document.

QUANTIFICATION OF EFFECTS

In the absence of adequate animal toxicity data, the ambient water criterion for acenaphthene of 0.02 ppm (0.02 mg/ℓ) was derived from human organoleptic data (U.S. EPA, 1980). The data were collected using responses of a panel of 14 judges who detected acenaphthene at a mean threshold of 0.08 ppm, with a range of 0.02-0.22 ppm (Lillard and Powers, 1975). The lowest level (0.02 ppm) was taken as the best estimate of a criterion level to prevent unpleasant odor from acenaphthene, with a caveat that the criterion has no demonstrated relationship to potential health effects. Although a 32-day, single-dose level gavage study involving rats and mice (Knobloch et al., 1969) and a 5-month subchronic, single-exposure level inhalation study of rats (Reshetyuk et al., 1970) were evaluated (U.S. EPA, 1980), they were rejected as a basis for deriving an oral RfD because of inappropriate experimental design and ambiguity in the reporting of data. The 90-day subchronic study reported by U.S. EPA (1989) provides data appropriate for deriving an oral RfD for acenaphthene. This study identified a NOAEL of 175 mg/kg/day in mice exposed by gavage for 90 days. A LOAEL of 350 mg/kg/day for hepatotoxicity including increased liver weight cholesterol levels and hepatocellular hypertrophy was also identified. An RfD of 0.06 mg/kg/day was verified by the Agency workgroup (11/15/89). The RfD was derived using the 175 mg/kg/day NOAEL and applying an uncertainty factor of 3000: 100 to account for inter- and intraspecies variation, 10 to account for the use of less-than-lifetime study and an additional uncertainty factor of 3 to account for the lack of reproductive and chronic data.

Ambient quality criteria for water and seafood or seafood only can be calculated using the verified RfD of 0.06 mg/kg/day. Assuming an average

daily consumption of 2 ℓ of water and 0.0065 g of contaminated fish and shellfish and applying a BCF value of 242 ℓ/kg, the criteria for the ingestion of water and seafood of 1.18 or 2.67 mg/ℓ for seafood only can be calculated.

It should be noted that these are health based criteria. The ambient water quality criteria based on organoleptic effects is 0.02 mg/ℓ.

EXISTING STANDARDS AND CRITERIA

The final RQ for acenaphthene is 100 pounds (U.S. EPA, 1986).

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